

## REMARKS/ARGUMENT

### Description of amendments and claim status

Claims 21-31, 67 and 68 are canceled. Claims 1, 5-9, 11, 12, 14 16-20, 57-62, 65, 66, 69 and 70 are pending after entry of this Amendment. Claim 30 was withdrawn from consideration under the September 30, 2007 Official Action. No new matter is introduced by this Amendment.

Applicant respectfully requests reconsideration and reexamination in view of the foregoing claim amendments and remarks presented below.

Claims 21-31, 67 and 68 are canceled. The rejections of these claims is therefore moot.

### Rejection of Independent Claim 1 under 35 U.S.C. § 103(a)

Claim 1 stands rejected as unpatentable under 35 U.S.C. § 103(a) in view *Reiss* (US 2003/0032963), and *Reiss* with *Barry* (US 2002/0037358).

Claim 1 is directed to a method of modifying a balloon of a catheter assembly, including the step of inflating a balloon of a catheter assembly to an inflated state wherein the inflated state is greater than a range of an intended expanded configuration of the balloon and less than a diameter or size at which the balloon becomes damaged or unsuitable for its intended use of insertion into a patient.

In the present action, the Office has maintained its reasons for rejecting Claim 1 set forth in the 5/15/07 Official Action. As discussed by Applicants in their prior response, Applicants understand that the Office's conclusion on the un-patentability of Claim 1 relies on a construction for the recited inflated state that includes any insignificant pressure increase over the inflated balloon described in the cited art. Thus, with this construction in hand, the Official Action concludes that because one of ordinary skill in the art would have expected similar results for a balloon inflated an insignificant amount over wholly inflated, as a balloon that is wholly inflated, Claim 1 would have been obvious. Applicants traverse this rejection for the same reasons as before, and also for the following reasons.

The Office has concluded that an inflated state greater than a range of an intended configuration can be interpreted as "one molecule of fluid more than" an intended expanded configuration. See 5/15/07 Office Action. As best understood, the Office has therefore found that

insignificant changes in balloon pressure changes above an intended pressure fall under the meaning of an inflated state greater than a range of an intended configurations. However, Applicant's specification provides a clear meaning for an inflated state greater than a range of an intended configuration in the disclosure:

Over or hyperinflation is defined as any diameter above intended expanded configuration but less than a diameter or size in which the balloon will be damaged or no longer suitable for its intended use.

Paragraph 13 of US Publication No. 2005/0226991 (emphasis added). Thus, an inflated state greater than a range of an intended configuration must have a greater diameter than the diameters associated with a range of intended expanded configuration. Applicants respectfully ask whether the Office has taken into account the disclosure on paragraph [0013], because it is unclear how "one molecule of fluid more than an intended use configuration" would be consistent with a definition based on the diameter of the balloon. If the Office's current construction is sustained in light of the above, then Applicants kindly ask that an explanation be provided for how "one molecule of fluid more" is consistent with "any diameter above intended expanded configuration . . .".

Applicants submit that the Office's unreasonably broad definition of "an inflated state greater than a range of an intended configuration" cannot be correct because Applicants' disclosure clearly precludes a difference between the two states as far more than a so-called difference in "one molecule of fluid". *See* page 5 of the Official Action. The Office has never proffered evidence from Applicants' specification or elsewhere for its construction. In contrast, Applicants point to clear support from the disclosure, which states that "Over or hyperinflation is defined as . . .". *See* paragraph [0013] (emphasis added).

Any increased diameter over a range of intended use diameters is significant. U.S. Pat. No. 5,585,926, cited as evidence of the state of the art to support the Office's rejection, shows one example of how the art considers an over-inflated or hyper-extended state as distinct from an intended use state. Thus, in addition to the reasons set forth in Applicants' prior response, the art cited by the Office evidences that one of ordinary skill would have not considered the so-called ranges of balloon pressures so close as to expect similar results.

For at least these reasons, Applicants request that the rejection under 35 U.S.C. § 103(a) be withdrawn and Claim 1 allowed.

Claims 5, 8, 9, 16, 18, 19, 62 and 65 depend from Claim 1 and are therefore allowable at least due to their dependence on Claim 1. Withdrawal of the rejections to Claims 5, 8, 9, 16, 18, 19, 62 and 65 and allowance of these claims is earnestly solicited. Claims 6, 7, 11, 12, 14, 17, 20 and 66 were withdrawn as being directed to a non-elected species. In light of the foregoing, Applicants respectfully request that Claims 6, 7, 11, 12, 14, 17, 20 and 66 be re-entered and allowed, at least because they depend from allowable subject matter.

Rejection of Independent Claim 57 under 35 U.S.C. § 103(a)

Claim 57 stands rejected as unpatentable in view of *Lim* (US 7,198,632) and *Barry*. As best understood, the Official Action has rejected Claim 57 because *Lim* discloses a membrane formed from a porous balloon material that receives a drug, and it would have been obvious to deposit that drug when the balloon is inflated in view of *Barry*. Applicants traverse this rejection for the following reasons.

As pointed out on page 12 of Applicants' 8/24/2007 response, Claim 57 is patentable over *Barry* for the same reasons that were given for Claims 21, 29 and 30. Now Claim 57 is rejected over *Lim* in combination with *Barry*.

Applicants traversed the rejection of Claim 57 in the prior action for two reasons, i.e., the reasons given for Claim 21, 29 and Claim 30. *See* page 12 of Applicants 8/24/2007 response. Applicants successfully traversed the Office's previous rejection because, like Claim 21 and 29, Claim 57 was directed to a method of modifying a balloon in which the "membrane" refers to the membrane of the balloon material, not a coating or layer placed over the balloon surface (as disclosed in *Barry*). Applicants amended Claim 57 by adding the feature of "enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly" to make this point more clear.

Applicants also traversed the rejection because Claim 57, like Claim 30, included the feature of pores formed in a membrane. Applicants also understood that this asserted difference was sufficiently clear from the claims. Claim 21 in the previous action recited

inflating a balloon of a catheter assembly to an inflated state, the balloon having a wall membrane enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly;

whereas Claim 57 in the previous action recited

inflating a balloon of a catheter assembly to an inflated state, the balloon having a wall membrane enclosed at one end of the catheter assembly such that the enclosed wall membrane allows the balloon to inflate and deflate on the catheter assembly, and pores formed in the wall membrane;

It is worth pointing out that “pores formed in the wall membrane” was a part of Claim 57 since it was introduced prior to Applicants’ filing of a Request for Continued Examination in this application. Thus, Claim 57 has been examined and then reconsidered. Nevertheless, the Office has never addressed its rationale for explaining where *Barry* and its progeny disclose the feature of “pores formed in the wall membrane”. Applicants respectfully request that the Office please provide a complete rationale for the continued rejection of this claim so that Applicants have a reasonable opportunity to address the continued concern that the Office has with Claim 57.

Applicants also cited to paragraphs [0011] and [0012] of the disclosure, which provided support for Claim 57. In those sections, Applicants describe an embodiment in which cavities or surface depots are formed by a manufacturing process. Hence, in the last response Applicants also pointed to the examples of balloons having the features described under Claim 57 as part of its traverse. Nevertheless, it appears that balloons like those disclosed in *Lim* and/or *Barry* are believed to teach the features of Claim 57. Applicants respectfully submit that Claim 57 is not obvious in view of these references.

As noted above, *Lim* discloses a porous balloon material, but there is no teaching or suggestion of a membrane with pores formed in the membrane. And *Barry* also does not teach or suggest a balloon membrane as described in Applicants’ claim, for the same reasons as provided in Applicants’ earlier response. The Office has therefore not established a *prima facie* case of obviousness for Claim 57 under 35 U.S.C. § 103(a) because the combined art does not at least teach every feature of Claim 57. For at least this reason, Applicants’ ask that the rejection of Claim 57 be withdrawn.

Rejection of Independent Claim 57 under 35 U.S.C. 102(b)

Claim 57 was previously not considered anticipated by *Barry*. However, in the present action it is believed that *Barry* does anticipate Claim 57. As best understood, the Official Action concludes that although *Barry* does not state that the Nylon balloon in his Example 9 is porous, Applicants' disclosure includes Nylon among the set of balloon material considered "porous". The Official Action concludes, therefore, that Claim 57 is anticipated by *Barry* because Nylon falls within Applicants' definition of a porous balloon material.

The disclosure of Nylon is set forth under paragraph [0011]. As just explained, this is the portion of the disclosure that Applicants cited in the previous action for examples of balloons that may be used to practice the method of Claim 57. This section also discloses examples of balloons that may be used to practice the methods of Claim 1 or canceled Claim 21. Hence, from these examples the balloon material suitable for the method of Claim 57 can be porous or non-porous balloon material. Nylon is one such example of a non-porous balloon that may be used to practice the method of Claim 57. In fact a Nylon balloon is one example of Claim 30, which refers to pores formed in a non-porous balloon material.

The Official Action has based its case for anticipation on the view that Applicants' intended meaning for porous includes Nylon. Applicants submit that for the reasons given above this is not the case. Nylon is a non-porous material under Applicants' definition. Accordingly, as *Barry* does not disclose a membrane with pores, at least because Nylon is not a porous balloon material, Claim 57 cannot be anticipated by *Barry*. Withdrawal of rejection under 35 U.S.C. § 102(b) is requested. Allowance of Claim 57 is requested.

Claims 59-61 depend from Claim 57 and are therefore allowable at least due to their dependence on Claim 57. Withdrawal of the rejections to Claims 59-61 and allowance of these claims is earnestly solicited. Claims 58, 69 and 70 were withdrawn as being directed to a non-elected species. In light of the foregoing, Applicants respectfully request that Claims 58, 69 and 70 be re-entered and allowed, at least due to their dependence on an allowable claim.


Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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